# Maryland Board of Pharmacy Public Board Meeting Minutes

Date: November 28, 2012

Name	Title	Present	Absent	Present	Absent
<b>Board Committee</b>					
Bradley-Baker, L.	Commissioner/Treasurer		✓	3	2
Chason, D.	Commissioner	✓		5	0
Finke, H.	Commissioner	✓		5	0
Gavgani, M. Z.	Commissioner	✓		4	1
Hammonds, S.	Commissioner		✓	3	2
Handelman, M.	Commissioner	✓		5	0
Israbian-Jamgochian, L.	Commissioner	✓		4	1
Matens, R.	Commissioner	✓		3	2
Souranis, M.	Commissioner/President	✓		5	0
St. Cyr, II, Z. W.	Commissioner	✓		5	0
Taylor, D.	Commissioner	✓		5	0
Taylor, R.	Commissioner/Secretary	✓		4	1
Board Counsel					
Bethman, L.	Board Counsel	✓		5	0
Felter, B.	Staff Attorney	✓		5	0
Board Staff					
Naesea, L.	<b>Executive Director</b>	✓		5	0
Wu, Y.	Compliance Manager	✓		4	1
James, D.	<b>Acting Licensing Manager</b>	✓	✓	3	0
Gaither, P.	Administration and Public Support	✓		4	1
	Manager				
Jeffers, A.	Legislation/Regulations Manager	<b>√</b>		5	0
Johnson, J	MIS Project Manager	✓		1	0

\*excused

Responsible		Action Due Date	Results
Party		(Assigned To)	
· · · · · · · · · · · · · · · · · · ·			
	9		
President	when the issue is addressed in the agenda.		
	at 9:42 a.m.		
	2 M. Carrania managed at all managing action to the internal and		
	before they leave the meeting.		
	3. Members of the Board with any conflict of interests		
	the Board.		
	4. M. Souranis reported that all handouts are to be returned		
	by attendees when they leave the meeting.	Motion to accept minutes as	Motion was
		submitted made by D.	approved.
		Taylor.	
	board meeting minutes.	•	
		W. St. Cyr, II.	
A. Empontino			1
*			
Naesea			
	·		
	•	Party  A. M. Souranis, Board President  Discussion  Members of the Board with a conflict of interest relating to any item on the agenda are advised to notify the Board at this time or when the issue is addressed in the agenda.  1. M. Souranis, President, called the Public Meeting to order at 9:42 a.m.  2. M. Souranis requested all meeting attendees to introduce themselves, to please sign the guest log and to indicate whether they would like continuing education credits before they leave the meeting.  3. Members of the Board with any conflict of interests relating to any item on the agenda were advised to notify the Board.  4. M. Souranis reported that all handouts are to be returned by attendees when they leave the meeting.  5. Review and approval of October 17, 2012, 2012 public board meeting minutes.  A. Executive Director, L.  Operations Update – L. Naesea introduced Isaac Kim, an intern with the Board of Pharmacy (BOP) from the	A. M. Souranis, Board tem on the agenda are advised in the agenda.  1. M. Souranis, President President  1. M. Souranis, President, called the Public Meeting to order at 9:42 a.m.  2. M. Souranis requested all meeting attendees to introduce themselves, to please sign the guest log and to indicate whether they would like continuing education credits before they leave the meeting.  3. Members of the Board with any conflict of interests relating to any item on the agenda were advised to notify the Board.  4. M. Souranis reported that all handouts are to be returned by attendees when they leave the meeting.  5. Review and approval of October 17, 2012, 2012 public board meeting minutes.  4. Executive Director, L. Naesea  4. Operations Update – L. Naesea introduced Isaac Kim, an intern with the Board of Pharmacy (BOP) from the University of Maryland Eastern Shore (UMES) School of Pharmacy. This is the BOP's first intern from the UMES School of Pharmacy. This is the BOP's first intern from the UMES School of Pharmacy. Mr. Kim has been with the BOP for an additional 2 and one-half weeks and will be with the BOP for an additional 2 and one-half weeks and will be with the BOP for an additional 2 and one-half weeks and will be with the BOP for an additional 2 and one-half weeks and will be with the BOP for an additional 2 and one-half weeks and will be with the BOP for an additional 2 and one-half weeks and will be with the BOP for an additional 2 and one-half weeks and will be with the BOP for an additional 2 and one-half weeks and will be with the BOP for an additional 2 and one-half weeks and will be with the BOP for an additional 2 and one-half weeks and will be with the BOP for an additional 2 and one-half weeks and will be with the BOP for an additional 2 and one-half weeks and will be with the BOP for an additional 2 and one-half weeks and will be with the BOP for an additional 2 and one-half weeks and will be with the BOP for an additional 2 and one-half weeks and will be with the BOP for an additional 2 and one-h

due to difficulty BOP staff is encountering in retrieving some statistical data with the new MIS database. This issue will be resolved in the near future as the Board now has a permanent MIS Manger to address this and other issues. L. Naesea apologized to all licensees that have had difficulty renewing their licenses as a result of the BOP's new MIS database. Most of the "kinks" have been resolved and the Board has mailed out most licenses printed using the new MIS system.

## • Meeting Updates :

On 10/18/2012 L. Naesea met with all Board Directors and Senator Hollinger to discuss upgrading the Patterson Avenue Shared Conference Room. When renovations are made to Patterson Avenue there will be an additional conference room added for the BOP. Discussions are ongoing and L. Naesea is working with the Department to get audio/video and MIS equipment permanently installed in one of the shared conference rooms, much like the MHCC conference room. As previously mentioned in last month's meeting the BOP will be moving to the Fifth Floor here at Patterson Avenue in the Spring of 2013 and additional meeting space will be created with that move.

- L. Naesea held a meeting with Pawan Kolapalli and Jack Ottensosser of System Automation, the MIS vendor. Mr. Ottensosser is working on setting up training for all of the Board's staff to further develop the staff's skills in using and manipulating the new system.
- L. Naesea met with Dr. Toyin Tofade, Associate Director
  of the Experiential Learning Program at the University of
  Maryland School of Pharmacy on November 13, 2012. Dr.
  Tofade wanted to introduce herself and learn more about
  the preceptor opportunities here at the BOP.
- On November 22, 2012 there was a briefing with Deputy Laura Herrera and Dr. Blyth regarding the meningitis

outbreak, both of DHMH Epidemiology and Infectious
Disease Unit. There has been one death and several
persons infected in Maryland by a sterile compounding
pharmacy in Massachusetts, the New England
Compounding Center. Board staff gave a briefing on the
Board's response and what the Board's planned steps.

Compliance Manager Wu attended a CDS Monitoring
meeting on October 28, 2012 to discuss recommendations

- Compliance Manager Wu attended a CDS Monitoring meeting on October 28, 2012 to discuss recommendations related to prescription pads. Further discussion will be held later in today's public board meeting.
- On November 24, 2012 L. Naesea received an award for 30 years of service to the State of Maryland
- D. Chason. and L. Naesea gave an interview to the Baltimore Sun Newspaper regarding the meningitis outbreak. The article which appeared on the Sun's online website November 18, 2012 was very favorable to the Board, however, the headline of the printed version on November 19, 2012 incorrectly stated "Maryland Board Resists U.S. Role in Regulation of Pharmacies." On November 26, 2012 the Sun published a letter from the Board as well as a retraction of its misleading headline. The BOP letter that was published on November 26, 2012 was titled" "Headline Mischaracterized the Board of Pharmacy's stance."
- Patricia Gaither and L. Naesea met with Janet Nugent, Director of Personnel for the Department of Health & Mental Hygiene. The meeting was scheduled quickly as Ms. Nugent is retiring at the end of December, 2012. The meeting was to get her advice on recruiting for a new pharmacist position and reorganizing the Board. L Naesea spoke with John Newman, DHMH liaison to the Department of Budget and Management. Mr. Newman suggested that the Board consider a special temporary position for a pharmacist to address the expansion in the

number of inspections of high risk pharmacies. This position is needed as hospital satellite pharmacies will be required to hold their own permits and be independently inspected. The Board needs pharmacist support to insure safety in these compounding pharmacies. Mr. Newman stated he would do whatever he could to support this position. L. Naesea, M. Souranis, H Finke and A. Jeffers also met with Delegate Hammens to request support for the Board's legislative initiatives in 2013. The Board continues to have concerned about inspection of compounding and satellite pharmacies. L. Naesea believes the Board will receive the support it needs; not only for the temporary position but also for the permanent position when we move forward with that request.

- L. Naesea met with Senator Hollinger and Secretary Sharfstein on November 14, 2012 to discuss state stats and the kind of reports the Secretary wants the Board to capture when reporting disciplinary and compliance matters in state stats. This information will be presented in our new format in the near future.
- L. Naesea took part in a conference call with NAPB November 27, 2012. NAPB will work with the Iowa BOP to inspect all non-resident pharmacies. L. Naesea discussed with Linda Bethman what information the BOP can share with the Iowa BOP for those non-resident pharmacies that are licensed in both Maryland and Iowa.
- L. Naesea received an invitation from Margaret A. Hamburg, Commissioner of the United States Food & Drug Administration (FDA) to participate in an intergovernmental working meeting on December 19, 2012 to provide perspective on the FDA's relationship with the states regarding compounding pharmacies and the best way to provide oversight of this industry going forward.

B. Administration & Public Support	Administration & Public Support Manager, P. Gaither	<ul> <li>P. Gaither reported, as previously mentioned, John Johnson has been hired as the Board's new MIS Manager with his start dated being today, November 28, 2012.</li> <li>In addition, the Board has received a PIN for the MIS Computer Network Specialist II position and the Board has received the list of eligible candidates for that position. The list and applications will be reviewed and selections made to schedule interviews.</li> <li>The Licensing Manager's position has been posted for 10 days as an In-House recruitment and the deadline for receiving applications was November 27, 2012. Four applications have been received and will be reviewed to schedule interviews.</li> <li>As mentioned in last month's Board Meeting, Yin Chan, inspector, has resigned and the Board has requested, and been granted, a freeze exemption for that Administrative Officer position. Recruitment information has been forwarded and the Board is waiting for the job to be posted.</li> </ul>	
C. MIS  D. Licensing	J. Johnson, MIS Manager  D. James, Acting Manager	John Johnson, the Board's new MIS Manager introduced himself and noted that he has worked for the State of Maryland for over 20 years at five different agencies. His most recent state agency was with the Department of Public Safety.  Monthly Statistics October, 2012: Complete Licensing Statistics Are not available this month.	

		Total Licensees: 20594	
		New Applications: 144	
		Renewals: 393 Pharmacists – 228 Technicians – 98	
		Students - 67	
E. Compliance	Y. Wu, Manager	1. Monthly Statistics for September, 2012	
		Complaints & Investigations:	
		<u>New -</u> 20	
		Resolved – 17	
		Percent of action within goal 15/17 =88%	
		Final disciplinary actions taken – 8	
		Reversal – 0	
		Summary Actions Taken - 0	
		Inspections: 72	
		Annual - 59	
		Opening - 8	
		Relocation - 4	
		Special Inv 1	
		Closing - 1 (performed by the Division of Drug Control)	
	Gil Cohen, PEAC	PEAC Update – 19 current cases year to date.  New Clients for October, 2012: 3, 2 Pharmacists and 1 Technician. Mr. Cohen reported that PEAC received a Soros Foundation grant through the Open Society Institute. The grant, totaling \$65,000.00 for one year, funds a community education project proposal. Funding in future years is contingent on project performance. A major goal of the project is to increase the desire for intervention early in the course of illness.	

F. Legislation &	A. Jeffers	MEETINGS:		
Regulations		1) November 7, 2012 Meningitis Briefing before HGO Attended by Dave Chason, LaVerne Naesea, and Anna Jeffers		
		Bd of Pharmacy Written Testimony Briefing on Meningitis Outbreak 110812  Three considerations for legislation to address regulation of out of	Motion by R. Matens to require all non-resident	Motion was approved.
		state compounding pharmacies:  a) Require accreditation of out of state compounding pharmacies by an accreditation organization that physically inspects those entities;	pharmacies to have annual inspections either by their home state or by an entity approved by the Board that	
		b) Require reporting requirements similar to the Massachusetts emergency regulation;	shows compliance with Maryland law. Motion was seconded by D. Taylor.	
		247 CMR Pharmacy Emergency Regs_As Adopted		
		c) Add to 12-403 the specific requirement that out of state compounding pharmacies comply with the Board's sterile pharmaceutical compounding regulations – COMAR 10.34.19.		
		After lengthy discussion, the Board recommended that all nonresident pharmacies be required to have annual inspections, if not by their home state, then by an entity approved by the Board that shows compliance with Maryland law.		
		The Board feels that only by annual inspections will the Board be assured that nonresident pharmacies are compliant with USP 797. Many states do not inspect, or do not inspect on a routine basis, putting Maryland residents at risk when receiving medications from those pharmacies.		
		The Board also recommends requiring nonresident pharmacies to report certain information to the Maryland Board. The Board's Practice Committee meets on December 12th and will consider what reporting requirements would be appropriate.		

# 2) Meetings Scheduled to Seek Sponsors and Support of Proposed Legislation

# (A) November 15<sup>th</sup> Meeting with Chairman Hammen.

Attended by Mike Souranis, Harry Finke, LaVerne Naesea, Anna Jeffers, and Isaac Kim

Two draft bills that the Board would like introduced were discussed.

1) Elimination of workmen's comp exemption from obtaining dispensing permits and annual inspections;

Chairman Hammen will find a sponsor for this legislation after the session begins.

2) Oversight of out of state compounding pharmacies;

Chairman Hammen is looking forward to the Board's recommendation for oversight of out of state compounding pharmacies. Voted on above.

#### B) November 19, 2012 HGO Special Briefing

Attended by Rodney Taylor, Lenna Israbian-Jamgochian, LaVerne Naesea, Anna Jeffers, and Isaac Kim.

- Vaccines Meeting; and The Chairman's draft legislation expands the administration of vaccines by pharmacists in Maryland to children age 11 and above with a prescription. Adults for CDC recommended immunizations and travel vaccines. The age for children might be raised to 13.
- Biosimilars Meeting. Most of the stakeholders did not think legislation which creates a substitution law specifically for biosimilars is necessary at this time. Stakeholders defer to the FDA on this issue.
- C) December 4, 2012 Drug Shortages Briefing before HGO.
- D) December 4, 2012 meeting scheduled with Chairman Carter Conway

Health Occupations - Service Members and Spouses - Processes for Temporary Licensure, Certification, and Registration.  Section 1-702(B)(1).  Board's preliminary position on the draft legislation is requested.  The Board approved supporting the concept of this legislation pending more information on the criteria for review by DHMH for alternate licensing requirements.  INQUIRY FROM THE VIRGINIA BOARD OF PHARMACY  What steps is MD taking or plans to take to address concerns regarding sterile compounding?  See the recommendation for legislation above.	Motion by L. Israbian-Jamgochian to support the concept of this legislation pending more information on the criteria for review by DHMH for alternate licensing requirements. Motion was seconded by D. Chason.	Motion was approved.
1) Maryland Board of Pharmacy Prescription Drug Repository Program Seventh Annual Report to the Governor and the General Assembly  Maryland Board of Pharmacy Prescription Drug Repository Program Seventh Annual Report to the Governor and the General Assembly  Board approval requested for the Seventh Annual Drug Repository Report	Motion by Legislative Committee to approve Maryland Board of Pharmacy Prescription Drug Repository Program Seventh Annual Report to the Governor and the General Assembly. Motion was seconded by M. Gavgani.	Motion was approved.

4	The Board approved the Seventh Annual Drug Repository Report.	1	<u> </u>
	2) CDS Monitoring Subcommittee recommendations for prescription requirements in Maryland	Motion by Legislative Committee to recommend	
		that_prescription pads be	
	CDS recommendations (rev 10-17-12) Carole Catalfo 111412  The Board did not recommend requiring tamper proof prescription pads because that would not solve the problem of forged prescriptions.  The Board did recommend the following:  1) Require that prescription pads are inventoried and secure;  2) Require patient ID for all CDS; and  3) What controls does the Board of Physicians have in place with respect to prescription drugs and diversion?	inventoried and secure; require patient ID for all CDS; and inquire as to what controls the Board of Physicians have in place with respect to prescription drugs and diversion.  Motion was seconded by H. Finke.	Motion was approved.
	3) Health Occupations – State Board of Naturopathic Medicine  Board comments requested;		
	Amendments to SB180 (Response to Board of Pharm).docx		
	Removes references to dispensing.		
	DLS Naturopathic Medicine report, 9.13.12.pdf		
	<u>sb0180t_3</u>		
	The Board is taking no position on this legislation as long as naturopathic physicians' scope of practice does not include dispensing.		
	REGULATIONS:		
	10.34.03 – Inpatient Institutional Pharmacies Board approval requested for proposal and to release for informal comment.	Motion by Legislative	

DRAFT 10.34.03.01 Satellite Pharmacies version 8 for 112812  Bd Mtg  The Board approved the proposal and approved releasing it for informal comment.  10.34.06 Reporting Pharmacist's and Pharmacy Technician's Mailing Address and Location of Employment  Proposal sent to OHCQ and MP for sign off 10/23/12.  10.34.11 - Disciplinary Monetary Penalties, and Civil Fines	Committee to approve Satellite Pharmacies proposal and to release it for informal comment. Motion was seconded by D. Chason.	Motion was approved.
Notice of Final Action signed 10/23/12 & returned to DHMH for sign-off. The Notice of Final Action is anticipated to be published 12/14/12 with an effective date of 12/24/12.  10.34.14 – Opening and Closing of Pharmacies and 10.34.30 – Change to Permit – Pharmacy or Distribution Permit Holder.  Proposal released for informal comment 9/25/12 through 10/12/12.  Board approval requested for responses to informal comments and submission of the proposed regulations.  The Board approved the response below to the Division of Drug Control and also approved submission of the proposal for publication.  DDC Informal Comment 10.34.14 and .30  Bd Response to DDC informal comment 10.34.14	Motion by Legislation Committee to approve response to the Division of Drug Control as stated in these minutes and to approve submission of 10.34.14 – Opening and Closing of Pharmacies and 10.34.30 – Change to Permit – Pharmacy or Distribution Permit Holder, for publication. Motion was seconded by D. Taylor.	Motion was approved.

Thank you for offering informal comments concerning the Maryland Board of Pharmacy's proposed revisions to COMAR 10.34.14 Opening and Closing of Pharmacies and COMAR 10.34.30 Change to Permit – Pharmacy or Distribution Permit Holder. The Board looks forward to working with the Division of Drug Control on implementation of COMAR 10.34.14 once the proposed revisions become effective. Thank you again for your thorough reading of and informal comments to the proposed revisions to COMAR 10.34.14 Opening and Closing of Pharmacies and COMAR 10.34.30 Change to Permit – Pharmacy or Distribution Permit Holder. The Board considered your comments at the November 28, 2012 Board Meeting and voted to submit COMAR 10.34.14 Opening and Closing of Pharmacies and COMAR 10.34.30 Change to Permit – Pharmacy or Distribution Permit Holder as proposed to the Department of Health and Mental Hygiene for approval and publication in the Maryland Register. 10.34.14 and 10.34.30 Release for Informal Comment 092512 10.34.22 – Licensing of Wholesale Prescription Drug or Device Distributors -Proposal sent to OHCQ and MP for sign off 10/22/12. 10.34.23 Pharmaceutical Services to Patients in **Comprehensive Care Facilities** Motion by Legislative Board approval requested for revisions that requires pharmacist Committee to release final check of interim boxes. 10.34.23 Pharmaceutical Motion was Services to Patients in approved.

Board approval requested to release for informal comments.	Comprehensive Care Facilities.	
The Board approved release of the proposal for informal comments.	T dominos.	
proposed-1-11 10.34.23		
10.34.29 – Drug Therapy Management		
Has been submitted as an Emergency Proposal.		
10.34.36 – Pharmaceutical Services to Residents in Assisted		
Living Programs and Group Homes -		
Published September 21, 2012. One comment received.	Motion by Legislative Committee to approve	
Board approval requested for the response to the comment and the re-proposal.	response to MACS and stated in these minutes and	Motion was approved.
	to approve submission of	**
The Board approved the response below to MACS and approved	the re-proposal of_10.34.36	
submission of the re-proposal for publication.	<ul> <li>Pharmaceutical Services</li> <li>to Residents in Assisted</li> </ul>	
MACS Comment Letter-Pharmacy Regs 10.22.12	Living Programs and Group Homes for publication.	
Board Response - Official Comment - 10.34.36 MACS	Motion was seconded by D.	
Thank you for submitting a comment concerning the proposed	Taylor.	
Code of Maryland Regulations (COMAR) 10.34.36		
Pharmaceutical Services to Residents in Assisted Living Programs		
and Group Homes, as published in 39:19 Md. R. 1266 - 1270		
(September 21, 2012). Below you will find the Board's response to		
your concerns.		
MACS expressed concerns regarding the statement in the		
economic impact indicating that the Board would inspect assisted		
living facilities and group homes. The Board apologizes for any		
confusion that this statement may have caused. The Board will		
revise the economic impact in its re-proposal to reflect that the		
Board will be inspecting the pharmacies that service assisted		

living facilities and group homes.

MACS indicated in its comment to the Board that Regulation .06 Medication and Device Distribution and Pharmaceutical Services, which requires 1) the pharmacist to be accountable for participating in an assisted living program's or group home's quality assurance improvement program; and 2) implementation of policies and decision of the committees of an assisted living program or group home, is burdensome for most group homes. As a result of MACS' comment the Board agrees and will re-propose Regulation .06 by separating those two requirements into a separate section where compliance will be optional. You will note in the attached re-proposal that the Board has change the requirement language of "shall" to the optional language of "may."

Although not included in MACS' comments, the Board will also re-propose Regulation .10 Quality Management, by separating assisted living and group homes into two separate sections A and B:

### .10 Quality Management.

<u>A.</u> The responsible pharmacist, in cooperation with the appropriate committee of the assisted living program [[[or group home]]], shall [[[be responsible for developing]]]

# develop

procedures for an ongoing quality management program that includes a mechanism for reviewing and evaluating pharmaceutical services as defined in this chapter and COMAR 10.07.14.29 where appropriate.

B. The responsible pharmacist, in cooperation with the		
appropriate committee of the group home, if applicable,		
may develop procedures for an ongoing quality		
management program that includes a mechanism for		
reviewing and evaluating pharmaceutical services as		
defined in this chapter.		
The Board would like to thank you again for your thorough reading of, and comments to, the proposed COMAR 10.34.36 Pharmaceutical Services to Residents in Assisted Living Programs and Group Homes. The Board considered your comments at the November 28, 2012 Board Meeting and voted to re-propose COMAR 10.34.36 to reflect the substantive changes outlined above.  Reproposal for COMAR 10.34.26.		
10.13. 01 – Dispensing of Prescription Drugs by a Licensee		
Board approval requested to release for informal comments.  COMAR 10.13.01 - Proposed Draft for Nov 28 Bd Meeting  This regulatory chapter has been put on hold until after the 2013 Legislative Session.	This matter was tabled, no action taken.	

III. Committee Reports	H. Finke, Chair,	1) Dr. Jennifer Gudeman, Ther-Rx Corporation	Motion by Practice Committee to approve letter	Motion was approved.
A. Practice Committee		Compounding of hydroxyprogesterone caproate injections	to Dr. Jennifer Gudeman of Ther-Rx Corporation as stated in these minutes. Motion was seconded by R. Matens.	
		Mo Board of Pharmacy newsletter august		
		AZ102012		
		FDA QA on Makena 062912		
		FDA Statement 061512		
		Draft Bd Response - Compounding of hydroxyprogesterone II		
		The Board approved the response below:		
		Thank you for contacting the Maryland Board of Pharmacy requesting that the Board notify Maryland pharmacists of the recent statements		
		made by the U.S. Food and Drug Administration (FDA) regarding the compounding of hydroxyprogesterone caproate injections.		
		The Board recognizes the June 15, 2012 statement from the Food and Drug Administration set forth below. The Maryland Pharmacy Act and Board of Pharmacy Regulations do not prohibit pharmacists from compounding in compliance with this statement.		
		On June 15, 2012, Food and Drug Administration (FDA) issued a statement indicating it will apply its normal enforcement		
		policies for pharmacies compounding hydroxyprogesterone caproate. In line with the FDA's statement, licensees are		
		reminded that 20 CSR 2220-2.200(9) provides: Compounding of drug products that are commercially available in the		
		marketplace or that are essentially copies of commercially available Federal Food and Drug Administration (FDA)		
		approved drug products is prohibited. There shall be sufficient documentation within		
		the prescription record of the pharmacy of the specific medical need for a particular variation of a commercially available		
		compound. Accordingly, licensees must have sufficient documentation of a specific medical need prior to compounding		

hydroxyprogesterone caproate in the future. 2) Dorene Miles, Cegedim Motion by Practice Motion was Cegedim - USB Flash Drive Committee to approve letter approved. to Dorene Miles of Fwd 10-655 avc prescription device question--Response 1 Cegedim as stated in these minutes. Motion was Re Research on devices seconded by M. Gavgani. Draft Bd Response - Rx Flash Device The Board approved the response below: Thank you for contacting the Maryland Board of Pharmacy concerning whether a company is required to be licensed as a wholesale distributor in Maryland if it provides a USB flash drive that has been designated as a prescription medical device. The company intends to use this prescription medical device as part of a disease state program in Maryland. The device is a USB flash drive that contains software for interfacing with certain hospital machines. When used with these machines, the software generates printed reports that help identify patients who may be overdue for a particular type of scan. Please be advised that although this device is designated as a prescription medical device, it appears to consist of software that interfaces with hospital technology. So long as the entity is following the Health Information Privacy and Accountability Act (HIPAA) regulations and Maryland privacy laws, it may provide this device without being a wholesale distributor. See Health-General Article, Title 4, Annotated Code of Maryland. http://mlis.state.md.us/asp/web statutes 2013.asp?ghg&4-101 Additionally, the Board and its committees do not endorse activities, products, systems or services. Entities are welcomed to share information with the Board regarding its activities, products, systems and/or services. However, receipt of the information by the Board does not represent the Board's approval or endorsement

		of the product, system or service.		
B. Licensing Committee	D. Chason Chair,	<ol> <li>Review of Pharmacist Applications: None</li> <li>Review of Pharmacy Technician Applications:         <ul> <li>Jermaine Gilmer</li> <li>Technician sent in application for reinstatement. Expired 08/31/2011. Following confirmation of npt working during the period expired, recommendation is to approve reinstatement.</li> </ul> </li> </ol>	Motion by Licensing Committee to approve reinstatement application of Jermaine Gilmer. Motion seconded by D. Taylor.	Motion was approved.
		• <u>Dawn Daniels</u> - Technician sent in application for reinstatement. Expired 08/31/2011. Technician previously didn't send in renewal and reinstatement fees Folowing confirmation of npt working during the period expired, recommendation is to approve reinstatement.	Motion by Licensing Committee to approve reinstatement application of Dawn Daniels. Motion seconded by M. Gavgani.	Motion was approved.
		<ul> <li>3) Review of Distributor Applications: None</li> <li>4) Review of Pharmacy Technicians Training Programs:</li> <li>• Kmart Pharmacy National Pharmacy Technician Training Program – Recommendation is to approve program.</li> </ul>	Motion by Licensing Committee to approve Kmart Pharmacy National Pharmacy Technician Training Program. Motion was seconded by D. Taylor	Motion was approved.
		<ul> <li>New Business:         <ul> <li>AMKA Pharmaceutical Services, Inc – The Board was copied with a letter sent by MHEC indicating that the technician training program was in violation of Education Article 11-202 with MHEC. MHEC directed AMKA to immediately cease and desist promoting their institution and offering training in Maryland. Program is not Board approved. Informational Only.</li> </ul> </li> </ul>	AMKA Pharmaceutical Services, Inc. was presented for information purposes only. No action was taken on this matter.	
		Online Renewal CE Approval Process – Discussion	Motion by Z. St. Cyr, II to	

Maryland National Capitol Homecare Association     Maryland National Capitol Homecare Association     MNCHA requested clarification on the need for Maryland HME providers who provide medical devices to hold a pharmacy license.  Recommendation is to send letter informing company that the Board is has appointed task force to evaluate distribution of medical devices.	add attestation question to hard copy of application as it appears on the on-line application. Motion was seconded by D. Chason.  Motion by Licensing Committee to send letter to MNCHA that Board is developing task force to evaluate distribution of medical devices. Motion was seconded by M. Gavgani.	Motion was approved.  Motion was approved.
• Ken Mercer at Northwest Hospital - Company asked if they would be required to hold a Maryland pharmacy license in order to supply pharmaceuticals to the residents in Levindale Geriatric Center and Courtland Gardens, if they have a pharmacy license with Sinai Hospital. Also, he asked whether the small room that acts as a stat dose pharmacy, and stores patients' prescriptions, need to be licensed as a pharmacy? Recommendation is to inform company that they do not have to be licensed as a separate pharmacy if the license held under Sinai is a full pharmacy permit; But if it is operating under a PW permit, they will have to inform the Board of an added classification. Regarding the small room, no permit is required as long as a licensed staff member administers these medications.	Motion by Licensing Committee is to inform company that they do not have to be licensed as a separate pharmacy if the license held under Sinai is a full pharmacy permit; But if it is operating under a PW permit, they will have to inform the Board of an added classification. Motion was seconded by M. Gavgani. Following discussion by the Board the Licensing Committee modified its recommendation and recommended that the answer token Mercer's first question remain the same (answer depends on current permit), and that regarding	Motion was approved.

• Requirement of Oral Competency Test - Response from Berlitz on offsite verification of oral competency test. Recommendation is to approve Berlitz proposal but add an emergency number for applicants to contact for technical support.	the second question, the company should be informed that if they provide pharmacy services out of the "STAT dose pharmacy," it needs to be permitted as a pharmacy.  Motion by Licensing Committee to approve Berlitz proposal using "Skype" as off-site oral verification process adding an emergency number for applicants to contact for technical support. Motion was seconded by D. Taylor.	Motion was approved.
• John Meyers - Applicant, John Meyers, did not have complete CE credits. He was short 5 CE's and 2 live. When notified, he requested a refund of his \$253 payment and requested his license be placed on a non renewed status. The former Licensing Manager informed the applicant that she would a process refund. The Board had the denied refund request and licensee appealed decision. Recommendation is to notify licensee of the option to submit CE to Board for approval but we cannot accept it until then and he has to now pay reinstatement fees.	Motion by Licensing Committee to notify John Meyers that he must pay reinstatement fee and he can submit CE to Board for review and possible approval. Motion was seconded by M. Gavgani.	Motion was approved.
Bruce Bergman – The licensee submitted a renewal application without the required live CE's. The licensee stated that he assumed that the courses he took were "Live" but were previously recorded. He is asking for a waiver to allow	Motion by Licensing Committee to deny request of Bruce Bergman and to inform him he must take 2 live CE credits and pay	Motion was approved.

		acceptance of the two courses as "Live" for renewal of pharmacist license. Recommendation is to deny request and inform licensee that he has to take 2 "live" CE's and pay reinstatement fees.	reinstatement fee. Motion was seconded by L. Israbian-Jamgochian.
C. Public Relations Committee  D. Disciplinary	L. Bradley-Baker, Chair	• Z. St. Cyr, II reported for the Public Relation Committee which met last week to discuss a number of topics. The Fall, 2012 BOP Newsletter has been sent to the printer and should be available soon. All reports for the 2012 Annual Report have been requested from BOP staff and asked that those reports be submitted by December 17, 2012. The committee has asked that all articles for submission to the Winter BOP Newsletter be submitted no later than December 21, 2012. The Committee is conducting a review of upcoming health fairs and events in which the BOP participated in 2012 to determine which events to continue participating in 2013. The CE Breakfast was very successful, 109 attendees. The committee has already begun discussion s for the 2013 CE Breakfast. Finally, the committee is continuing to investigate sites outside of Baltimore at which to hold a few public board meetings so there is more opportunity for the public to attend and gives greater Board visibility  Disciplinary Committee Update – No update this month.	
D. Discipinary	Jamgochian, Chair	Disciplinary Committee Opeace Tro apeace this month.	
E. Emergency Preparedness Task Force	D. Taylor, Chair	<ul> <li>Emergency Preparedness Task Force Update:         <ul> <li>During hurricane Sandy D. Taylor was in contact with DHMH and LaVerne Naesea as the liaison for Emergency Preparedness Task Force with the Board. The overtness level was raised from 4 to 3.</li> <li>D. Taylor has been asked to speak at the University of Maryland School of Pharmacy at Baltimore as well as at the University of Maryland Eastern Shore School of Pharmacy. He will discuss the pharmacist's role in emergency preparedness</li> </ul> </li> </ul>	

IV. Other Business &	M. Souranis,	No Other business to report this month.		
FYI	President			
V. Adjournment	M. Souranis, Board President	The Public Meeting was adjourned at 12:20 p.m.  At 1:14p.m. M. Souranis convened a Closed Public Session to conduct a medical review of technician applications.  C. The Closed Public Session was adjourned at 1:17 P.M. Immediately thereafter, M. Souranis convened an Administrative Session for purposes of discussing confidential disciplinary cases. With the exception of cases requiring recusals, the Board members present at the Public Meeting continued to participate in the Administrative Session.	Motion by D. Chason, to adjourn the Public Board meeting pursuant to State Government Article 10-508)a)(13) and (7) for the purpose of engaging in medical review committee review deliberation regarding confidential matters in applications Meeting. The motion was seconded by Z. St. Cyr, II.	Motion was approved.